DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1
Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, on 03/05/19, I observed two operators place (b) (4) ___ in ISO 5 hoods ___ without wiping with (b) (6) ___ during the production of Milrinone 60mg, Rx (b) (6) ___ and TPN 3:1, Rx (b) (6) ___.

OBSERVATION 2
Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, on 03/05/19, I observed the door from the non-classified area to the ISO 7 ante room open at the same time the door from the ISO 7 ante room to the ISO 7 ___ . This occurred during the production of Vancomycin HCL, Rx (b) (6) ___ and TPN 3:1, Rx (b) (6) ___.

OBSERVATION 3
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.
Specifically, media fills are not representative of the maximum batch size for aseptic operations for syringes and IV bags. For example, your firm produced (b) (4) syringes of (b) (4) Rx (b) (6) on 12/12/18, however your media fill consists of (b) (4) vials, (b) (4) syringes, and (b) (4) IV bag.

*DATES OF INSPECTION
3/05/2019 (Tue), 3/06/2019 (Wed), 3/07/2019 (Thu), 3/08/2019 (Fri), 3/12/2019 (Tue)